510(k) Summary for K130422

APR 4 2013

Tornier, Inc. Phantom Fiber BioFiber Suture

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name: Phantom Fiber BioFiber Suture

Common name: Suture, recombinant technology

Classification Number/ Classification name/Product code:Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology are class II devices under 21 CFR § 878.4494 (product code NWJ) and are classified by the General and Plastic Surgery Devices Panel.

2) Submitter

Tornier, Inc.
10801 Nesbitt Avenue
Bloomington, MN 55437
Registration Number: 9100540

3) Company contact

Lael J. Pickett
Regulatory Affairs
Tornier, Inc.
10801 Nesbitt Avenue
Bloomington, MN 55437 USA
Telephone: 612-219-7350/Fax: 952-426-7601
Email: lpickett@tornier.com

4) Classification

Device class: Class II

Classification panel: General and Plastic Surgery Devices

Product code: NWJ

Special Controls: Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology

5) Legally Marketed Device to which Equivalence is Claimed

Tornier BioFiber Suture (K122487).

6) Comparison to Predicate Device

Feature	**From:** Tornier BioFiber Suture (K122487)	**To:** Tornier Phantom Fiber BioFiber Suture
Indications for Use	For use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.	Same.
Design		
Composition	P4HB	Same
Needles attached	Available with and without needles attached	Same
USP Size	Size 2	Same
Design	Braided	Same
Colors	Un-dyed (natural) or dyed (D&C Violet No. 2)	Same
Performance		
USP <861> Suture diameter	Compliant for size 2, except that the diameter is slightly larger	Same
USP <871> Suture Needle Attachment	Compliant for size 2	Same
USP <881> Tensile Strength	Compliant for size 2	Same

7) Device description

Tornier, Inc. Phantom Fiber BioFiber Suture is a n absorbable, braided, sterile, surgical USP size 2 suture composed of poly(4-hydrobutyrate) (P4HB) with cyanoacrylate adhesive tipped ends. Phantom Fiber BioFiber Suture is braided for optimal handling properties and is available either dyed (D&C Violet No. 2) or un-dyed (natural), with and without pre-attached needles.

8) Indications for Use

Phantom Fiber BioFiber Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

9) Summary of technologies

Phantom Fiber BioFiber Suture was subjected to FDA Special Controls required USP testing such as; suture tensile strength, suture diameter, suture needle attachment strength; as well as non USP testing. The non USP testing included in-vivo degradation testing of product strength over time and residual molecular weight. The results of this non-clinical testing allow us to conclude that the Phantom Fiber BioFiber Suture described in this submission is substantially equivalent and as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Tornier, Inc.
% Ms. Lael J. Pickett
Regulatory Affairs
10801 Nesbitt Avenue
Bloomington, Minnesota 55437

Letter dated: April 4, 2013

Re: K130422
Trade/Device Name: Phantom Fiber Biofiber Suture
Regulation Number: 21 CFR 878.4494
Regulation Name: Absorbable poly (hydroxybutyrate) surgical suture produced by recombinant DNA technology
Regulatory Class: Class II
Product Code: NWJ
Dated: March 06, 2013
Received: March 12, 2013

Dear Ms. Pickett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130422

Device Name: Tornier, Inc. Phantom Fiber™ BioFiber™ Suture

Indications for Use

Phantom Fiber BioFiber Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use ___X____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)
Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130422